REMARKS

Claims 1-13 and 21-34 are pending in this application. By this Amendment, claims 1 and 2 are amended. The amendments introduce no new matter as they serve only to better clarify the subject matter recited in the claims. Reconsideration based on the above amendments and the following remarks is respectfully requested.

Applicants appreciate the courtesies shown to Applicants' representative by Examiner Mallari in the many telephone interviews that the Examiner accepted from Applicants' representative during the lengthy period of suspension of this application. The indulgences of Examiner Mallari in attempting to explain the delay in examination of this application are appreciated.

The Office Action, on page 2, for the first time five years of prosecution of this application, rejects claims 1 and 2 under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. While Applicants do not concede the propriety or the timeliness of this assertion, claims 1 and 2 are voluntarily amended to obviate this rejection.

Accordingly, reconsideration and withdrawal of the rejection of claims 1 and 2 under 35 U.S.C. §101 are respectfully requested.

The Office Action, on page 6, indicates that claims 33 and 34 recite allowable subject matter. Specifically, these claims are indicated as being allowable rewritten in independent form including all of the features of the base claim and any intervening claims. Applicants appreciate this indication of allowability but respectfully submit that at least independent claim 3, from which these claims depend, is allowable for at least the reasons indicated below.

The Office Action, on page 3, rejects claims 1-5, 10, 11, 21-23, 28, 29 and 32 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,221,026 to Phillips. Applicants understand this to be a rejection under 35 U.S.C. §103(a) based on the language included on

page 3, and specifically, the concession that Phillips does not teach testing for hepatic diseases. This rejection is respectfully traversed.

Phillips does not disclose a data-processing section to test for hepatic disease and/or hepatic cirrhosis, Applicants respectfully submit that Phillips cannot be read to teach, or even to have suggested, all of the features of at least independent claims 3 and 21. In response to Applicants previously having made this argument over the Phillips reference based on the substance of the rejection set forth in the November 17, 2004 Office Action, and in discussion with the Examiner, this Office Action asserts that "the examiner takes official notice that it is well known in the art for a doctor or other clinical staff to test for multiple related diseases, particularly upon suspicion of a single disease, in order to provide the most accurate diagnosis and effective treatment for the patient." The Office Action goes on to draw an overly broad relationship between diseases for which Phillips explicitly detects or tests, and testing for hepatic diseases. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to use the method and apparatus of Phillips to test for liver disease since some undefined relationships can be drawn between the diseases that Phillips tests for and those which it does not, which the Office Action asserts are "related diseases." This analysis of the Office Action fails for at least the following reason.

While it is true that doctors may test for multiple related diseases, it is also equally true that those doctors will use certain data of a certain component only for diagnosis of the diseases, selecting that component based on a known relationship between the disease and the component. Applicants believe that the Office Action draws an overly broad conclusion in asserting Official Notice to render obvious the subject matter of the pending claims in confusing a manner by which a doctor may have a suspicion that a patient is suffering from a certain disease relating to that doctor believing that the patient may also suffer from another disease, and discerning the other disease with a method of testing of the first disease using

data of a certain component which is known to be relevant to the detection of the first disease, and not necessarily relevant to detection of the second disease.

Further, in taking Official Notice, no documentary evidence is provided to support the Examiner's conclusions. MPEP §2144.03 indicates that such a methodology "is permissible only in some circumstances . . . these circumstances should be rare." MPEP §2144.03 indicates that official notice unsupported by documentary evidence should only be taken by the Examiner where the "facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well known." This standard is not met in this Office Action.

For at least the failures in the Office Action (1) in overly broadly applying the concept of Official Notice; and (2) in failing to present objective evidence of record as a basis for the Official Notice, the analysis of the Office Action regarding the obviousness of the above-enumerated claims necessarily fails.

Additionally, it should be noted that the November 17, 2004 Office Action, on page 6, affirmatively stated Phillips "fails to teach testing for hepatic diseases and analyzing a result of the quantification of isoproponal." Applicants should be permitted to rely on the analysis of the Patent Office in asserting the Office's conclusion regarding what a particular reference is affirmatively considered as "failing to teach."

Accordingly, reconsideration and withdrawal of the rejection of claims 1-5, 10, 11, 21-23, 28, 29 and 32 under 35 U.S.C. §102(e) as being anticipated by Phillips are respectfully requested.

The Office Action, on page 4, rejects claims 6-9, 12, 13, 24-27, 30 and 31 under 35 U.S.C. §103(a) as being unpatentable over Phillips in view of U.S. Patent No. 5,573,005 to Ueda. This rejection is respectfully traversed.

Ueda, in its detailed disclosure of a breath collection apparatus, does not overcome the shortfalls in the application of Phillips to at least independent claims 3 and 21. As such, claims 6-9, 12, 13, 24-27, 30 and 31 are also not taught, nor would they have been suggested by, the combination of the applied references for at least the respective dependence of these claims on independent claims 3 and 21, as well as for the separately patentable subject matter that these claims recite.

Accordingly, reconsideration and withdrawal of the rejection of claims 6-9, 12, 13, 24-27, 30 and 31 under 35 U.S.C. §103(a) as being unpatentable over the combination of the applied references are respectfully requested.

The Office Action, on the second page 2 headed "**37 C.F.R. 1.105 REQUIREMENT FOR INFORMATION**," asserts that certain additional information is required from the Applicants to further examination of this application. Specifically, in paragraph 2a, the Office Action indicates that the reference referred to at the top of page 2 in Applicants' disclosure is necessary to further reexamination of this application. This analysis fails for at least the following reasons.

First, the timeliness of this request places it at question. This application has been in prosecution for almost five years. Claims 1 and 2 were indicated as allowed previously. The examination of this application to date has been incredibly strained. This strained approach has included suspension of examination of this application for an inordinate period of time with the explanation that other prior art may be forthcoming. There is no basis for the current request under 37 C.F.R. §1.105 based first on the ill-timed tendering of the request.

Second, the specific reference requested is referred to in the Background section of Applicants' disclosure where it states that "in recent years, there is proposed a method for testing for various disorders by measuring metabolites in breath. Such a method is described, for example in Yasuhiro Mitsui, "detection systems of trace components in breath", bulletin

of S14-5 Showa 62 National Convention of Institute of Electrical Engineers of Japan (1987)) [sic]." The background of Applicants' disclosure at page 2 then goes on to discuss the shortfall of the methodology discussed in that reference. For at least the totality of this disclosure, the requested reference is not material to the patentability of the subject matter of the pending claims. The record of examination of this application is replete with references both disclosed by the Applicants, and considered by the Patent Office, that teach varying methodologies of breath-based testing. Few of these references, like the reference disclosed in the background of Applicants' disclosure, are specifically material to the subject matter of the pending claims.

In response to the request under 37 C.F.R. §1.105, Applicants respectfully submit that no other publications and/or reference materials are available that (1) meet the requirements of 37 C.F.R. §1.105; or (2) Applicants consider material to the patentability of the subject matter of the pending claims. Any implication in, for example, paragraph 6 on page 5 of this portion of the Office Action indicating in any manner that Applicants have not been candid, or have not acted in good faith, in meeting their responsibilities for disclosure under Rule 56 are both regrettable and without basis.

In view of the foregoing, Applicants respectfully submit that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-13 and 21-32, in addition to the indicated allowable subject matter in claims 33 and 34, are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number set forth below.

Respectfully submitted,

James A. Oliff
Registration No. 27,075

Daniel A. Tanner, III
Registration No. 54,734

JAO:DAT/cfr

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OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

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